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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/512,090 | 02/11/2005 | Hee-Yong Lee | P26228 | 7911 |
| 7055 | 7590 | 10/15/2007 | EXAMINER | |
| GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191 | | | ROGERS, JAMES WILLIAM | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/15/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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| | | |
|------------------------------|------------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/512,090 | LEE ET AL. |
| | Examiner James W. Rogers, Ph.D. | Art Unit 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment to the claims filed 09/14/2007 have been entered.

Applicants have amended claim 7:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (WO 01/28524 A1, disclosed by applicants), for the reasons set forth in the office action filed 03/16/2007.

Response to Arguments

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive. Applicants assert that the formulation of Scott is fundamentally different than their formulation because Scott teaches microspheres coated with lipids and fatty acids that are constitutionally different than their claimed invention.

The relevance of this assertion is unclear. Applicants claims are drawn to a solid formulation comprising a protein and sulfated polysaccharide encapsulated with hydrophobic material. The claims as currently amended do not preclude microspheres containing therapeutic proteins, a complexing agent including sulfated polysaccharides, and further coated by a fatty acid or lipid. Applicants claims as currently amended do not preclude the hydrophobic material (lipids and fatty acids) being present on a

coating. In fact encapsulation generally refers to particle(s) or a core surrounded by a coating. Since applicant's claims state that the mixture of protein and sulfated polysaccharide are encapsulated with hydrophobic material the Scott reference anticipates applicants currently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (WO 01/28524 A1, disclosed by applicants).

Applicant's arguments filed 09/14/2007 have been fully considered but they are not persuasive. Applicants assert that as stated above Scott does not disclose the particular structure of applicants claimed invention nor would the prior art teach how to arrive at the particular structure of applicants claimed invention. Applicants also assert that there is nothing that would have led to the choice of spray drying or any other method to arrive at the presently claimed structure.

The relevance of these assertions is unclear. Applicant's claims are drawn to a solid formulation comprising a protein and sulfated polysaccharide encapsulated with hydrophobic material. The claims as currently amended do not preclude microspheres

containing therapeutic proteins, a complexing agent including sulfated polysaccharides, and further coated by a fatty acid or lipid. Applicants claims as currently amended do not preclude the hydrophobic material (lipids and fatty acids) being present on a coating. In fact encapsulation generally refers to particle(s) or a core surrounded by a coating. Regarding applicants assertion that there is no motivation to use any method disclosed within Scott to make their composition, the relevance of this assertion is unclear. As described above applicants claims do not preclude the microparticles of Scott, therefore any method described within Scott would be capable of producing the composition as currently claimed by applicants. As described previously since Scott describes that spray drying is routinely used to dry microparticles it would have been obvious to the skilled artisan that spray drying could be used to dry the microparticles recited.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER